

BECKMAN

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Summary of Safety & Effectiveness
IMAGE™ Immunochemistry System Alpha-1-Microglobulin (A1M) Reagent

1.0 Submitted By:

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2.0 Date Submitted:

16 December 1996

3.0 Device Name(s):

3.1 Proprietary Names

IMAGE™ Immunochemistry System Alpha-1-Microglobulin (A1M) Reagent

3.2 Classification Name

Not classified

4.0 Predicate Device(s):

IMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMAGE System Alpha-1-Microglobulin (A1M) Reagent	Beckman Alpha-1- Microglobulin A1M Reagent	Beckman Instruments, Inc.	K933078

Beckman Instruments, Inc.

5.0 Description:

The IMMAGE Immunochemistry System A1M Reagent in conjunction with Beckman Urine Protein Calibrator, is intended for use in the quantitative determination of alpha-1-microglobulin in human urine samples on Beckman's IMMAGE™ Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Alpha-1-Microglobulin (A1M) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Urine Protein Calibrator, is intended for the quantitative determination of alpha-1-microglobulin in urine by rate nephelometry.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System A1M Reagent	Analytic Range	Same as Beckman Alpha-1-Microglobulin Reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System A1M Reagent	Antigen excess testing	IMMAGE A1M has antigen excess testing solution included in the reagent cartridge, while the Beckman Alpha-1-Microglobulin Reagent requires off-line preparation of the solution.
	Antibody concentration	IMMAGE A1M has a higher antibody concentration than the Beckman Alpha-1-Microglobulin Reagent

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Reagent on the Array® 360 System to the IMAGE System Reagent.

Method Comparison Study Results IMAGE Alpha-1-Microglobulin (A1M) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMAGE A1M Reagent	Urine	0.961	0.10	0.993	123	Beckman Alpha-1-Microglobulin Reagent

Stability Study Results

Reagent	Product Claim
IMAGE A1M	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.77	0.021	2.8	80
Level 2	3.05	0.056	1.8	80
Level 3	6.59	0.161	2.4	80
Total Imprecision				
Level 1	0.77	0.031	4.1	80
Level 2	3.05	0.061	2.0	80
Level 3	6.59	0.194	2.9	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.